DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Medist International
Bernard F. Grisoni, Ph.D.
9160 Highway 64
Suite 12
Lakeland, Tennessee 38002

July 26, 2017

Re: K000019
Trade/Device Name: Single Size Tendon Spacer
Regulation Number: 21 CFR 888.3025
Regulation Name: Passive tendon prosthesis
Regulatory Class: Class II
Product Code: HXA
Dated: January 3, 2000
Received: January 4, 2000

Dear Dr. Grisoni:

This letter corrects our substantially equivalent letter of March 29, 2000.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K000019

Device Name: Single Size Tendon Spacer

Indication For Use:

Surgical indications for the Single Size Tendon Spacers include: Scarred or adhering tendons due to trauma or failed primary repair. Absence of tendon sheath. Scarred or adherent non-functional tendon pulleys. Ruptured tendon. The device is single use, temporary implantation for 2 to 6 months.

Concurrence of CDRH, Office of Device Evaluation (ODE)

James R. Lechner.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000019

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

K 000019

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510(K) SUMMARY

(As required by section 21 CFR 807.92(c))

Submitter's name:	Medist International
Submitter's address:	9160 Highway 64, Suite 12, Lakeland, TN 38002
Submitter's telephone number:	(901) 380-9411
Contact Person:	Bernard F. Grisoni
Submission date:	January 3, 2000
Trade Name:	Single size Tendon Spacer (name subject to change)
Common Name:	Tendon Spacer
Classification Name:	Prosthesis, Tendon, Passive
Legally marketed predicate devices:	Wright Medical Technology Swanson Tendon Spacer

Device description:
The Single Size Tendon Spacer is designed to facilitate the two-step tendon reconstruction surgery. The device is 50 cm long, and its oval cross section increases progressively over its length from 3.0 x 1.5 mm to 3.0 mm x 6.0 mm. The spacer slope is designed to match shapes and dimensions of the digital canal. The spacers are made of high performance medical grade silicone elastomer containing barium sulfate to provide radio-opacity. During the first stage of the reconstruction surgery, the spacer is placed into the reconstructed tendon bed and slid until optimum fit is achieved. The tendon is attached to the distal phalanx and the proximal spacer end is left free in the palm or forelimb. Excess spacer material is cut off. The second stage of surgery is performed 2 to 6 months later, once an appropriate pseudo-sheath has been created around the spacer, and tissues are soft and pliable. The spacer is then removed and replaced by a permanent active tendon autograft. The device is not intended as permanent implant or to function as a replacement for a ligament or tendon.

Indication for use:
Scarred or adhering tendons due to trauma or failed primary repair.
Absence of tendon sheath.
Scarred or adherent non-functional tendon pulleys.
Ruptured tendon.

Technological characteristics:
The Single Size Tendon Spacer device has the equivalent technological characteristics (i.e. chemical composition, and mechanical strength) to the predicate device.

Performance data:
Studies demonstrated that the Single Size Tendon Spacer devices have the equivalent mechanical strength and biocompatibility performances to the predicate device.

Basis for substantial equivalence:
The Single Size Tendon Spacer device is safe and effective because they are equivalent to the predicate devices in terms of chemical composition, indication of use, and product performances.